# Before the Federal Communications Commission Washington, DC 20554

In the Matter of:	)	
Office of Engineering and Technology Seeks Comment on Sensible Medical Innovations Ltd's Request for Waiver of Part	)	ET Docket No. 18-39
15 Ultra-Wideband Rules for a Medical		
Imaging System		

# COMMENTS OF THE NATIONAL PUBLIC SAFETY TELECOMMUNICATIONS COUNCIL

The National Public Safety Telecommunications Council (NPSTC) submits these comments in response to the Public Notice in the above captioned proceeding. The Public Notice seeks comment on a request for waiver of several Part 15 rules that define the regulations for ultra-wideband technology. Sensible Medical Innovations Ltd has requested the waivers to enable certification and marketing of its non-invasive medical imaging system for use in monitoring and measuring lung fluid levels in congestive heart failure patients. For the reasons addressed herein, NPSTC supports a grant of the requested waivers.

<sup>&</sup>lt;sup>1</sup> Public Notice, Office of Engineering and Technology Seeks Comment on Sensible Medical Innovations Ltd's Request for Waiver of Part 15 Ultra-Wideband Rules for a Medical Imaging System, ET Docket No. 18-39, released February 9, 2018.

## **The National Public Safety Telecommunications Council**

The National Public Safety Telecommunications Council is a federation of public safety organizations whose mission is to improve public safety communications and interoperability through collaborative leadership. NPSTC pursues the role of resource and advocate for public safety organizations in the United States on matters relating to public safety telecommunications. NPSTC has promoted implementation of the Public Safety Wireless Advisory Committee (PSWAC) and the 700 MHz Public Safety National Coordination Committee (NCC) recommendations. NPSTC explores technologies and public policy involving public safety telecommunications, analyzes the ramifications of particular issues and submits comments to governmental bodies with the objective of furthering public safety telecommunications worldwide. NPSTC serves as a standing forum for the exchange of ideas and information for effective public safety telecommunications.

The following 16 organizations serve on NPSTC's Governing Board:<sup>2</sup>

American Association of State Highway and Transportation Officials

American Radio Relay League

Association of Fish and Wildlife Agencies

Association of Public-Safety Communications Officials-International

Forestry Conservation Communications Association

International Association of Chiefs of Police

International Association of Emergency Managers

International Association of Fire Chiefs

International Municipal Signal Association

National Association of State Chief Information Officers

National Association of State Emergency Medical Services Officials

National Association of State Foresters

National Association of State Technology Directors

National Council of Statewide Interoperability Coordinators

National Emergency Number Association

National Sheriffs' Association

<sup>&</sup>lt;sup>2</sup> These comments represent the views of the NPSTC Governing Board member organizations.

Several federal agencies are liaison members of NPSTC. These include the Department of Homeland Security (the Federal Emergency Management Agency, the Office of Emergency Communications, the Office for Interoperability and Compatibility, and the SAFECOM Program); Department of Commerce (National Telecommunications and Information Administration); Department of the Interior; and the Department of Justice (National Institute of Justice, Communications Technology Program). Also, Public Safety Europe is a liaison member. NPSTC has relationships with associate members: The Canadian Interoperability Technology Interest Group (CITIG) and the Utilities Technology Council (UTC), and affiliate members: The Alliance for Telecommunications Industry Solutions (ATIS), Open Mobile Alliance (OMA), Telecommunications Industry Association (TIA), TETRA Critical Communications Association (TCCA), and Project 25 Technology Interest Group (PTIG).

#### **NPSTC Comments**

Sensible Medical Innovations Ltd. (Sensible) filed a request for waiver of the Commission's rules to allow the marketing and operation of its ReDs medical imaging system to provide lung fluid measurements in congestive heart failure patients. The ReDs medical imaging system can provide these measurements in a non-invasive way because electromagnetic signals are used to perform the measurements. A low power transmitting sensor and a companion receiver are placed on opposite sides of a patient's chest. The dielectric properties of the lung, which varies depending on the amount of fluid, alters the electromagnetic waves. The ReDs system measures these changes to calculate the fluid level in the lungs. Based on the description in the waiver request, these devices would be used by patients either at home or in medical facilities, while under a doctor's care and oversight.

Sensible seeks a waiver of the technical requirements in sections 15.31(c), 15.503(d), 15.513(a), 15.521(d), and 15.525 of the rules for its ReDs system. These rules specify the frequency range allowed and establish other technical requirements that relate primarily to detailed measurement and testing procedures for ultra-wideband devices. Also, the rules require that <u>users</u> of UWB imaging devices coordinate the deployment of their systems with the National Telecommunications and Information Administration (NTIA) through the Commission.

Sensible states that the frequency range specified in Section 15.513 (a) does not allow proper penetration of the body, an essential requirement for the ReDs lung fluid measurement system. Sensible also notes that user (i.e., patient) coordination with NTIA through the Commission as required under Section 15.525 is impractical. Finally, Sensible cites various technical reasons the ReDs system does not meet the fractional bandwidth requirements in Section 15.503(d) and the specific measurement procedures in Sections 15.521(d) and 15.31(c).

In responding to the request for comments, NPSTC is guided primarily by its view that a non-invasive medical system to measure lung fluid in congestive heart failure patients provides positive benefits to patients, and potentially to emergency medical service (EMS) personnel that may need to serve these patients. In its request, Sensible notes that about 5.7 million people in the U.S. suffer from congestive heart failure (CHF) and that "pulmonary congestion is the most common cause of worsening heart failure leading to hospitalization." Sensible cites studies that have shown hospital readmission rates for CHF can be reduced through monitoring and early detection. Sensible therefore concludes that accurate monitoring of lung fluid volume can assist in guiding optimal treatment and prevent readmission after hospitalization.

<sup>&</sup>lt;sup>3</sup> Sensible Medical Innovations request for waiver, submitted January 16, 2018 at page 2.

NPSTC is not an expert in the design of ultra-wideband devices and has not conducted an exhaustive study of the interference potential for the proposed ReDs system. However, NPSTC believes that any significant interference from the ReDs system to public safety communications is unlikely, based on several factors involving frequency range, duty cycle and the use of spread spectrum technology.

First, Sensible states that its ReDs System must operate in the range of 1005 to 1709 MHz. This span of frequencies generally falls outside the VHF, UHF, 700 MHz and 800 MHz frequency bands allocated for public safety communications and interoperability. Sensible's requested frequency range of 1005 to 1709 MHz also falls outside of the frequency bands specified in the Commission's rules for ultra-wideband surveillance systems that can be operated by law enforcement, fire and rescue officials, public utilities and industrial entities.<sup>4</sup> The ultra-wideband rules provide that a fixed imaging surveillance system used by these entities must be contained within the 1990 MHz to 10,600 MHz frequency range. Therefore, Sensible's proposed system also should not overlap ultra-wideband fixed surveillance systems.

Second, the ReDs system should have a relatively confined pattern of RF energy, given the transmitting and receiving units are separated only by the thickness of a patient's chest. These sensors are part of a shielded vest the patient wears. Sensible's waiver request specifically states that "The sensors are shielded from all sides except for the body-attached side." Accordingly, it appears any signals travelling away from the body would be minimized.

Third, Sensible states that the ReDs device operates with a low 2% daily operation duty cycle and less than 0.1% actual transmission daily duty cycle at any given frequency. According to the waiver request, the ReDs transmitting device would scan up to 90 seconds from 1 to 20 times per

<sup>&</sup>lt;sup>4</sup> See section 15.511 of the rules.

<sup>&</sup>lt;sup>5</sup> Sensible Medical Innovations request for waiver at page 4.

day, depending on the managed care plan for a given patient. Finally, Sensible notes that the ReDs system uses frequency hopping technology which spreads the power over different frequencies, creating a low average power.<sup>6</sup>

We believe these design parameters all would contribute to a low risk of interference to public safety communications. We look forward to additional interference analysis, if any, submitted by other commenters in the proceeding. NPSTC has examined the waiver request in the context of benefit to the public and any potential interference primarily to state or local public safety communications. We agree with Sensible that it is impractical for users, i.e., patients, to coordinate operations of these devices with NTIA through the Commission. Therefore, we recommend the Commission coordinate up front with NTIA to help ensure potential impact to Federal bands also is addressed.

Finally, as an additional protection, we recommend the Commission consider whether the requested waiver grants need to be conditioned to require that Sensible must take expeditious action should interference occur, despite the apparent relatively low risk. Should interference actually occur, licensees may need assistance from the Commission's field offices to locate and confirm the source.

### **Conclusion**

NPSTC supports grant of the waivers requested by Sensible Medical Innovations. In offering this support, NPSTC is guided primarily by its view that a non-invasive medical system to measure lung fluid in congestive heart failure patients provides positive benefits to patients, and potentially to emergency medical service (EMS) personnel that may need to serve these patients.

<sup>&</sup>lt;sup>6</sup> Sensible Medical Innovations request for waiver at page 11.

Also, NPSTC believes multiple technical factors including the specific frequency range used, a low duty cycle and reliance on spread spectrum technology would contribute to a low risk of interference to public safety communications. Should interference occur despite the apparent relatively low risk, NPSTC believes that Sensible Medical Innovations, Ltd. would need to take steps expeditiously to resolve the problem. Accordingly, NPSTC recommends the Commission determine whether a non-interference condition is needed if the requested waivers are granted.

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March 12, 2018